

DETAILED ACTION

Formal Matters

Applicant's amendments filed on March 07, 2011 are acknowledged and have been considered. .
Claims 1-6, 13-19, and 24 are pending. Claims 13-15 and 24 are under consideration in the instant office action. Claims 1-6 and 16-19 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 7-12 and 20-23 and 25-27 are cancelled.

Withdrawn Rejection

The rejections applied in the previous office action under 35 U.S.C. 112, first paragraph are hereby withdrawn as per the cancellation of claim 27.

Corrected Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Applicant's claim of foreign priority to JP 2003-273176 is GRANTED because the English translation of the Japanese language document has been provided.

According to 35 C.F.R. 1.55 (a) (4)(i)(C) an English language translation of a non-English language foreign application is not required except: (A) When the application is involved in an interference (see § 41.202 of this title), (B) When necessary to overcome the date of a reference relied upon by the examiner, or **(C) When specifically required by the examiner.** In the instant case the examiner specifically asks for the translation of the above recited foreign documents in order to determine whether they contain subject matter that enables the instantly claimed invention. Additionally, according to 35 U.S.C. 372 (b) (3) **the Director may require a verification of the translation of the international application or any other document pertaining to the application if the application or other document was filed in a language other than English.** Furthermore according to 35 U.S.C. 119 (b) (3) the Director may require a certified copy of the original foreign application, specification, and drawings upon which it is based, **a translation if not in the English language,** and such other information as the Director considers necessary. Any such certification shall be made by the foreign intellectual property authority in which the foreign application was filed and show the date of the application and of the filing of the specification and other papers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 13-15 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch et al., (US Patent 5759581, published on June 2, 1998) and Van Soest et al., (WO 00/40617, published on July 13, 2000), as evidenced by Kesselmanns et al., (US Patent No. 6822091, published on November 23, 2004), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicant argues that the method of Van Soest et al. requires a cross-linking step. Neither the claims nor Baensch et al. mention cross-linking. In addition, Van Soest et al. describes that small starch particles having a particle size of 50nm to 100pm are highly desirable (page 1, lines 5-6 of Van Soest et al.). In fact, the Examples of Van Soest et al. only disclose starch particles with a particle size of less than 600nm or 1-10 microns. Therefore, applicants believe that Van Soest et al. teaches away from a starch powder with a large particle diameter.

These assertions are not found persuasive because applicant is resorting to attacking the references individually while the rejections are based on the combined teachings of Baensch et al., and Van Soest et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Contrary to applicant's assertions Van Soest et al., clearly teach a method for the preparation of starch particles in a two-phase system comprising the steps of a) a preparation of the first phase comprising dispersing the starch in water b) preparation of a dispersion or emulsion of the first phase in a second liquid phase c) crosslinking of the starch present d) separating the starch particles (see abstract). **Starch particles of very small particle size can be produced in controlled manner by means of this method** (see abstract). Van Soest et al., on page 7, lines 17-20 teach as follows:

The particle size of these particles is between 50 nm and 100 µm. The particle size is dependent on, inter alia, starch and cross-linking agent type and concentration, reaction time and the type of non-solvent. This method as well offers the advantage that the particle size can be adjusted by adjusting the process conditions, including the various components.

Van Soest et al., teach starch particle sizes in overlapping manner.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Applicant is clearly resorting to a piecemeal analysis of the prior art by ignoring other embodiments wherein the examiner depend for rejecting the particle size limitation of the claims. Furthermore, as clearly described by Van Soest et al.,

Art Unit: 1619

the particle size can be adjusted by adjusting the process conditions including the various components which is a clear evidence that optimizing the particle size of the starch particles is within the purview of the skilled artisan.

It must be noticed that for Van Soest et al., to be a proper prior art that is combinable with Baensch et al., neither the claims nor Baensch et al., do not necessarily have to teach or recite cross-linking the particles. First, applicant use the transitional phrase "comprises" in the claim recitation which is an open-ended language. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising, 'the terms containing' and mixture' are open-ended."). Baensch et al., is silent regarding cross-linking of the particles. This silence cannot be equated to teaching away. On the contrary it is noticed that one of ordinary skill in the art knowing that cross-linking of a given particle enhances structural integrity and stability would not be discouraged from looking the teachings of Van Soest et al. Crosslinking, therefore, is not precluded. The broadest reasonable interpretation of the claims would include both cross-linked and uncross-linked starch particles. Furthermore, as applicant already pointed out, Baensch et al., already teach starch particles which are not cross-linked. Moreover, applicant's point is unclear because the instant claims are silent as to the crosslinking of the particles and Van Soest et al., was not cited for crosslinking the particles. It is unclear what relevance the teaching of Van Soest et al, regarding crosslinking, has to do with the instant rejection.

Applicant also asserts that even if Van Soest et al., did suggest a larger particle diameter, Baensch et al. prohibits any increase in the particle size. Baensch et al. teaches that the starch particles disclosed in the reference are intended to be used as a fat substitute. Specifically, column 1, line 65 through column 2, line 3 of the reference describe: The purpose of the present invention is therefore to provide a new kind of food grade texture agent which presents all the characteristics to be usable as a fat and/or oil replacer, especially to produce a fatty mouth-feel and which can be produced in a relatively easy and inexpensive manner avoiding the use of solvents and/or other chemicals.

These assertions are not found persuasive because the above recitation that applicant recites neither teaches away from making larger particle size starch particles nor mentions anything about particle size.

Applicant also asserts Baensch et al. also makes it very clear that a small particle diameter is important to achieve a good fat replacement. Baensch et al. teaches away from a larger particle diameter. Column 1, lines 39-54 of the reference describe the particle size as follows (with emphasis added):

[A] good fat-mimetic system tries to achieve the viscous-lubricitious-absorptive profile of the fat itself. Since this cannot be readily accomplished with any single ingredient except for the synthetic fat substitutes, the most practical way to accomplish this is by using a combination of materials that can supply the desired sensory properties. They generally consist in a combination of water with thickening agent, soluble bulking agents and/or microparticulate components, with or without surface active lipids, the whole producing a creamy texture. The microparticulates provide a ball-bearing effect which improves and smoothes out the flow properties of the fat-replacer system and thus enhances the fatty perception of the food. They are usually insoluble materials, typically smaller than 3 microns, which are not perceived as particles by the tongue. In this excerpt, Baensch makes it clear that prior art usually used a particle diameter smaller than 3 microns.

These assertions are not found persuasive because Baensch et al., clearly is setting forth the state of the prior art wherein smaller particle size materials such as microcrystalline cellulose with sizes typically smaller than 3 microns which are not perceived as particles by the tongue have been known to be used in the art. These teachings neither teach away from making larger particle size starch particles nor mention anything about particle size. On the contrary as applicant recognized it Baensch et al., teach a food grade texture agent in the form of thermally stabilized swelling resistant and non-crystalline particles of high amylose starch, which present a gelled soft structure, in which the amylose content of the starch is between 40 and 70%, and in which 90% of the **particles have a diameter in the range of 5 to 30 microns** (see abstract). It must be recognized that the particle size is larger than 3 microns as taught previously in the prior art as set forth in the background section of Baensch et al. It is clear evidence that Baensch et al., is not against larger particle size ranges.

Applicant also asserts that Baensch et al. describes at column 2, lines 52-61 that the particles being proposed in the reference have a slightly larger diameter.

As the examiner describes above the larger particle size taught by Baensch et al., is a clear evidence that Baensch et al., is not against larger particle sizes.

Applicant also asserts that there are numerous places in the reference, which make it very clear that the particle size is extremely important to achieve the desired mouth texture. For example, column 7, lines 29-31 provides: The particle size of the rice flour is important with regard to sensory properties (graininess) and structure formation (gel strength).

The examiner did not dispute that fact that the particle size could be an important parameter. However, the above recitation does not exclude larger particle sizes as clearly taught Van Soest et al., either.

*On the other hand, Van Soest et al. describes that the starch particles proposed therein have a very different use. Page 7, line 30 through page 8, line 2 provides: The starch particles can be used, inter alia, in paper, textiles, explosives, foams, adhesives, hot melts, detergents, hydrogels, fertilisers, **foods, artificial odours and flavourings**, pharmaceutical and cosmetic products, tissues, soil improvers, pesticides, coatings, coatings removable by a mild treatment, for instance by means of enzymes or hot water, paints, inks, toners, organic reactions, catalysis, ceramics and diagnostic agents. The quantities to be used are the quantities customary for the use concerned. It is difficult to imagine that any of these uses could be mistaken for dietary fat.*

These assertions are not found persuasive because for Van Soest et al. a proper prior art that is combinable with Baensch et al., it does not necessarily have to teach the exact same use of Baensch et al. The fact that Van Soest et al. clearly teach the particles can be used in foods, artificial odors and flavorings is evidence that van Soest et al. teach an overlapping subject matter in an analogous art.

Applicant also asserts that perhaps the Examiner believes that because Baensch et al. heats in the presence of water, Baensch et al. would also release amylose and amylopectin, as claimed. Baensch et al. describes that heating in the presence of water causes the effects described at column 3, line 23-29 as follows: The conditions used according to the present invention are aimed to a partial gelatinization of the high amylose starch and full gelatinization of the starch of cereal flour. Full gelatinization of the high amylose starch, e.g. by high temperatures, as well as complete disruption and loss of integrity of the high amylose starch granules by applying high pressure or high shear mixing should be avoided. At column 2, lines 48-53, Baensch et al. describes that the crystal structure is not destroyed as follows: The particulate product of the invention is thus obtained in the form of grains having a gelled soft

structure, which retained in fact the non crystalline structure of the starting starch used. The particles have not been chemically modified nor altered by the controlled thermal and mechanical treatment, and have proven to be resistant to shearing, heating (up to 125°C.) and acid, as well as swelling resistant, for example in aqueous medium up to 120° C. Maintaining the crystalline structure is the opposite releasing amylose and amylopectin to the exteriors of the starch particles. The particulate product of the invention is thus obtained in the form of grains having a gelled soft structure, which retained in fact the non crystalline structure of the starting starch used. The particles have not been chemically modified nor altered by the controlled thermal and mechanical treatment, and have proven to be resistant to shearing, heating (up to 125°C.) and acid, as well as swelling resistant, for example in aqueous medium up to 120° C. Maintaining the crystalline structure is the opposite releasing amylose and amylopectin to the exteriors of the starch particles.

These assertions are not found persuasive because the above recitations by no means either explicitly or implicitly talk or can be related to amylose and amylopectin being prevented to be on the exterior of the particles. The teachings of full gelatinization of the high amylose starch, e.g. by high temperatures, as well as complete disruption and loss of integrity of the high amylose starch granules by applying high pressure or high shear mixing should be avoided by Baensch et al., cannot be equated to mean that the amylose and amylopectin would not be on the exterior of the particles rather it just means high temperature, high pressure, and high shear mixing is not recommended since it will result in complete disruption and loss of integrity of the particles. The examiner failed to understand how this teaching can be interpreted to mean on Baensch et al., the amylose and amylopectin cannot be on the exterior. As clearly described by the examiner Baensch et al., teach all the required steps of the instantly claimed invention except that the Baensch et al., do not explicitly teach starch particle sizes as recited in claim 13 which is clearly cured by the teachings of Van Soest et al. Therefore, if the required steps that the instant invention claims and the steps of Baensch et al., are found to be substantially similar it is reasonable to expect that those structural features that applicant recite would necessarily happen on the particles of Baensch et al., since the starch particles are prepared following substantially similar steps. Similarly, the teaching by Baensch et al., about maintaining the crystal structure of the particles has nothing to do with the amylopectin or amylose being on the exterior of the particles. It is a property highly controlled by the types of steps that are applied during the preparation of the particles. Applicant has not established that maintaining the crystalline structure is opposite to, or even inconsistent with, releasing amylose and amylopectin to the exterior of the starch particles. Applicant has not provided any

Art Unit: 1619

objective evidence regarding the amount of amylose and amylopectin on the exterior of the starch particles of Baensch et al. Since both the instantly claimed starch particles and the starch particles of Baensch et al. are both heated in water, they are both expected to have the same content of amylose and amylopectin. Furthermore, the instantly claimed percentage of water (40%) is close to the percentage of water taught by Baensch et al. (about 10-30%). Moreover, potato tubers inherently contain 20% amylose and 80% amylopectin, therefore, starch particles from potato tubers are also comprised of amylose and amylopectin. There is no reason or record to suppose that starch particles from potato tubers would have the amylose and amylopectin somehow exclusively or even mostly on the interior of the starch particles, therefore, starch particles from potato tubers are expected to meet the instantly claimed limitation even without the step of heating with water. Moreover, as already pointed out Baensch et al., like the instantly claimed starch particles are both heated in water, therefore, absent evidence to the contrary, they are expected to have the same properties including the percentage of amylose and amylopectin present on the exterior of the starch particles.

Applicant also asserts that the present invention, which releases the amylose and amylopectin, uses significantly more water than the method of Baensch et al., which retains the amylose and amylopectin. The following excerpts from paragraphs [0066] and [0069] Baensch et al. uses much less water. Column 6, lines 8-20 of Baensch et al. describe that the starch is heated in the presence of 10-30% water, as follows: of the published application indicate that the amount of water should be 40% by weight or more.

These assertions are not found persuasive because the aqueous phase as taught by Baensch et al., which is about 10 to 30% is close enough to render obvious the amount of 40% or more as recited in the instant amended claim because about 30% clearly meets to the minimum 40%. A *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Moreover, based on (see MPEP 2144.05 *In re Aller*, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)) “differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation.” The optimization of the amount of water is within the purview of the skilled artisan.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on 571-272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

6/6/11

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647